

§ 493.1814

42 CFR Ch. IV (10–1–99 Edition)

(c) In addition, if HCFA has reason to believe that the continuation of any activity by any laboratory (either the entire laboratory operation or any specialty or subspecialty of testing) would constitute a significant hazard to the public health, HCFA may bring suit and seek a temporary injunction or restraining order against continuation of that activity by the laboratory, regardless of the type of CLIA certificate the laboratory has and of whether it is State-exempt.

§ 493.1814 Action when deficiencies are at the condition level but do not pose immediate jeopardy.

If a laboratory has condition level deficiencies that do not pose immediate jeopardy, the following rules apply:

(a) *Initial action.* (1) HCFA may cancel the laboratory's approval to receive Medicare payment for its services.

(2) HCFA may suspend, limit, or revoke the laboratory's CLIA certificate.

(3) If HCFA does not impose a principal sanction under paragraph (a)(1) or (a)(2) of this section, it imposes one or more alternative sanctions. In the case of unsuccessful participation in proficiency testing, HCFA may impose the training and technical assistance requirement set forth at § 493.1838 in lieu of, or in addition to, one or more alternative sanctions.

(b) *Failure to correct condition level deficiencies.* If HCFA imposes alternative sanctions for condition level deficiencies that do not pose immediate jeopardy, and the laboratory does not correct the condition level deficiencies within 12 months after the last day of inspection, HCFA—

(1) Cancels the laboratory's approval to receive Medicare payment for its services, and discontinues the Medicare payment sanctions as of the day cancellation is effective.

(2) Following a revisit which indicates that the laboratory has not corrected its condition level deficiencies, notifies the laboratory that it proposes to suspend, limit, or revoke the certificate, as specified in § 493.1816(b), and the laboratory's right to hearing; and

(3) May impose (or continue, if already imposed) any alternative sanctions that do not pertain to Medicare

payments. (Sanctions imposed under the authority of section 353 of the PHS Act may continue for more than 12 months from the last date of inspection, while a hearing on the proposed suspension, limitation, or revocation of the certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures is pending.)

(c) *Action after hearing.* If a hearing decision upholds a proposed suspension, limitation, or revocation of a laboratory's CLIA certificate, HCFA discontinues any alternative sanctions as of the day it makes the suspension, limitation, or revocation effective.

[57 FR 7237, Feb. 28, 1992, as amended at 60 FR 20051, Apr. 24, 1995]

§ 493.1816 Action when deficiencies are not at the condition level.

If a laboratory has deficiencies, that are not at the condition level, the following rules apply:

(a) *Initial action.* The laboratory must submit a plan of correction that is acceptable to HCFA in content and time frames.

(b) *Failure to correct deficiencies.* If, on revisit, it is found that the laboratory has not corrected the deficiencies within 12 months after the last day of inspection, the following rules apply:

(1) HCFA cancels the laboratory's approval to receive Medicare payment for its services.

(2) HCFA notifies the laboratory of its intent to suspend, limit, or revoke the laboratory's CLIA certificate and of the laboratory's right to a hearing.

§ 493.1820 Ensuring timely correction of deficiencies.

(a) *Timing of visits.* HCFA, the State survey agency or other HCFA agent may visit the laboratory at any time to evaluate progress, and at the end of the period to determine whether all corrections have been made.

(b) *Deficiencies corrected before a visit.* If during a visit, a laboratory produces credible evidence that it achieved compliance before the visit, the sanctions are lifted as of that earlier date.

(c) *Failure to correct deficiencies.* If during a visit it is found that the laboratory has not corrected its deficiencies, HCFA may propose to suspend, limit, or revoke the laboratory's CLIA certificate.

(d) *Additional time for correcting lower level deficiencies* not at the condition level. If at the end of the plan of correction period all condition level deficiencies have been corrected, and there are deficiencies, that are not at the condition level, HCFA may request a revised plan of correction. The revised plan may not extend beyond 12 months from the last day of the inspection that originally identified the cited deficiencies.

(e) *Persistence of deficiencies.* If at the end of the period covered by the plan of correction, the laboratory still has deficiencies, the rules of §§493.1814 and 493.1816 apply.

§493.1826 Suspension of part of Medicare payments.

(a) *Application.* (1) HCFA may impose this sanction if a laboratory—

(i) Is found to have condition level deficiencies with respect to one or more specialties or subspecialties of tests; and

(ii) Agrees (in return for not having its Medicare approval cancelled immediately) not to charge Medicare beneficiaries or their private insurance carriers for the services for which Medicare payment is suspended.

(2) HCFA suspends Medicare payment for those specialties or subspecialties of tests for which the laboratory is out of compliance with Federal requirements.

(b) *Procedures.* Before imposing this sanction, HCFA provides notice of sanction and opportunity to respond in accordance with §493.1810.

(c) *Duration and effect of sanction.* This sanction continues until the laboratory corrects the condition level deficiencies or HCFA cancels the laboratory's approval to receive Medicare payment for its services, but in no event longer than 12 months.

(1) If the laboratory corrects all condition level deficiencies, HCFA resumes Medicare payment effective for all services furnished on or after the date the deficiencies are corrected.

(2) [Reserved]

[57 FR 7237, Feb. 28, 1992; 57 FR 35761, Aug. 11, 1992]

§493.1828 Suspension of all Medicare payments.

(a) *Application.* (1) HCFA may suspend payment for all Medicare-approved laboratory services when the laboratory has condition level deficiencies.

(2) HCFA suspends payment for all Medicare covered laboratory services when the following conditions are met:

(i) Either—

(A) The laboratory has not corrected its condition level deficiencies included in the plan of correction within 3 months from the last date of inspection; or

(B) The laboratory has been found to have the same condition level deficiencies during three consecutive inspections; and

(ii) The laboratory has chosen (in return for not having its Medicare approval immediately cancelled), to not charge Medicare beneficiaries or their private insurance carriers for services for which Medicare payment is suspended.

(3) HCFA suspends payment for services furnished on and after the effective date of sanction.

(b) *Procedures.* Before imposing this sanction, HCFA provides notice of sanction and opportunity to respond in accordance with §493.1810.

(c) *Duration and effect of sanction.* (1) Suspension of payment continues until all condition level deficiencies are corrected, but never beyond twelve months.

(2) If all the deficiencies are not corrected by the end of the 12 month period, HCFA cancels the laboratory's approval to receive Medicare payment for its services.

§493.1832 Directed plan of correction and directed portion of a plan of correction.

(a) *Application.* HCFA may impose a directed plan of correction as an alternative sanction for any laboratory that has condition level deficiencies. If HCFA does not impose a directed plan of correction as an alternative sanction for a laboratory that has condition